

NIH POLICY MANUAL

1820 - SELECTION OF EXTRAMURAL AWARD INSTRUMENT--GRANT, COOPERATIVE AGREEMENT, OR CONTRACT

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A. Purpose:

This issuance establishes NIH policy for selecting the appropriate award instrument for conducting extramural research and development (R&D) and training activities. It incorporates provisions of Public Law 95-224, the Federal Grant and Cooperative Agreement Act of 1977, and, in conjunction with NIH Manual [4815](#), implements for NIH R&D programs the concepts expressed in HHS Grants Administration Manual (GAM) Chapters 1-01 and 1-02, and PHS Grants Administration Chapters 1-01 and 1-02, with guidance specific to NIH extramural R&D programs and their needs.

B. Background:

The National Institutes of Health accomplishes its missions through intramural and extramural activities. Contract, grant, and cooperative agreement instruments formalize the terms and conditions and the nature of mutual agreements between NIH awarding components and extramural performers. While all these types of instruments are used to further the statutory purposes of the awarding Bureau, Institute or Division (BID), they also reflect the different relationships established between the parties. The choice among the grant, cooperative agreement or contract award instruments in any given circumstances must therefore be made carefully, using uniform criteria.

In February, 1978, the President signed the Federal Grant and Cooperative Agreement Act of 1977, P.L. 95-224. (The Act was amended by P.L. 97-258, September 13, 1982.) The Act establishes Government-wide criteria to distinguish between Federal procurement and assistance relationships with other parties, and it emphasizes that the choice of award instrument should be based on the purpose of the agency-recipient relationship, characteristics of the legal instruments, and related standards and conditions. Under the Act:

- Procurement contracts are used when the principal purpose of the transaction is the acquisition of property or services for the direct benefit or use of the Federal Government.
- Assistance awards are indicated when the principal purpose of the transaction is to transfer money, property, or services to a recipient to accomplish a public

purpose of support or stimulation authorized by law. Under assistance relationships:

1. Grants are used when no substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.
2. Cooperative agreements are used when substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the assisted activity.

References:

1. Public Law 95-224, Federal Grant and Cooperative Agreement Act of 1977, as amended by Public Law 97-258, Title 31 U.S.C. Chapter 63
2. Office of Management and Budget--Implementation of Federal Grant and Cooperative Agreement Act of 1977--Final OMB Guidance (43 FR 36860-65, August 18, 1978)
3. HHS Acquisition Regulation, 48 CFR 307.70--Considerations in Selecting an Award Instrument
4. HHS Grants Administration Manual, Chapters 1-01--Distinguishing Procurement and Assistance Relationships, and 1-02--Selection of Assistance Instruction (sic)- Grants and Cooperative Agreements
5. PHS Grants Administration Manual, Chapters 1-01--Guidelines for Selecting Award Instrument, Contract, Grant, or Cooperative Agreement, and 1-02--Use of Cooperative Agreements
6. NIH Manual Chapter [4110](#)--Request for Applications (RFAs)
7. NIH Manual Chapter [4815](#)--Use of Cooperative Agreements

D. Applicability:

This policy applies to all NIH extramural R&D and training projects, but not to agreements under which only direct Federal cash assistance to individuals is provided, or for which statutory requirements supersede policy requirements.

E. Definitions:

The following definitions apply to terms as used specifically in this release, and supplement the more general terms used in HHS Grants Administration Manual Chapters 1-01 and 1-02 and PHS Grants Administration Chapters 1-01 and 1-02.

1. Research- Systematic search or intensive study directed towards fuller scientific knowledge or understanding. In "basic research" the primary

motivation is the pursuit of knowledge for its own sake, e.g., understanding natural laws or systems, with no specific application necessarily foreseen other than long-term potential for fundamental results relevant to NIH missions.

"Applied research" is directed towards the practical application of knowledge or understanding to advance specific NIH missions.

2. Development- Systematic use of knowledge and understanding gained from research, directed towards creating useful materials, devices, systems, or methods to meet functional or economic feasibility requirements set by NIH. Development includes design of equipment prototypes and demonstration of processes but excludes routine production, quality control, and testing.

3. Acquisition- The purchase, lease, or barter of property or services for the direct benefit or use of the NIH or other Government agencies, including Government dissemination to third parties or the public. Acquisition establishes a procurement relationship under which the rights and duties of the NIH as buyer, and of the performer as seller, are defined.

4. Assistance- The award of money, property, services, or anything of value to a recipient to accomplish a public purpose of support or stimulation authorized by Federal statute. Assistance relationships are generally expressed less formally and in less detail than for procurements.

5. R&D Contract- An award instrument establishing a binding legal acquisition relationship between NIH and a recipient, obligating the latter to furnish R&D studies, services, or other end-products, whose functional qualities are defined as precisely as possible, and binding NIH to provide payment therefore. NIH R&D contracts customarily procure research, development, resources, and related activities, and the NIH role is that of "purchaser."

6. Research/Training Grant- An award instrument establishing an assistance relationship between NIH and a recipient, in which no substantial programmatic involvement is anticipated between NIH and the recipient during performance of the contemplated activity. NIH assists, supports, and/or stimulates recipients in their conduct of research, resource, training, and related projects, to accomplish a public purpose of mutual interest to NIH and the recipients, the NIH role being that of "patron."

7. Cooperative Agreement- An award instrument establishing an assistance relationship between NIH and a recipient, in which substantial programmatic involvement is anticipated between NIH and the recipient during performance of the contemplated activity. NIH assists, supports, and/or stimulates, and is involved substantially with recipients in conducting projects similar in program intent to those for grants, by facilitating performance of the effort in a "partner" role.

8. Substantial Programmatic Involvement- NIH scientific or program staff technical assistance, advice, coordination, and other program actions supporting recipients of cooperative agreements during the conduct of an activity, above and beyond the levels required normally for program stewardship of grants, but without dominating the relationship. Thus, substantial involvement includes:

- cooperation, coordination, or participation assisting awardees in performing project activities, e.g., development of research protocols; data collection, analyses, and interpretations; or re-establishment of objectives during course of a project;
- option to halt* a project activity if technical performance requirements are not met or if program objectives have already been met;
- review or approval* of one stage of a project before work may begin on a subsequent stage during a current approved project period;
- assistance with or approval* of provisions or the selection of contractors or subawardees under the assistance award, and in the selection of key project personnel other than principal investigators of projects or sub-projects;
- technical monitoring to permit specified kinds or directions of the work, including approval* of changes in experimental approaches;
- participation on committees or in other functions responsible for helping to guide the course of long-term projects or activities.

(*Paragraph H.2.a. notes the need for special review procedures to arbitrate disagreements between NIH and awardees.)

Conversely, substantial programmatic involvement does not include, e.g.:

- enforcement of general statutory, regulatory, or administrative assistance policy requirements;
- approval of awardee plans prior to award, or review of performance after completion;
- evaluation of progress by reviews of technical or fiscal reports or by site visits, to determine that performance is consistent with objectives, terms, and conditions of the award;

- technical assistance requested by awardees, or unanticipated procedures to correct programmatic or financial deficiencies in awardees' performance;
- scientific/technical discussions with awardees, or actions to facilitate or expedite interactions between awardees, e.g., organizing and holding meetings of investigators.

9. Program - A coherent organized assembly of NIH plans, activities, and resources directed towards accomplishing an established NIH mission.

10. Project - An identified activity of an NIH program, involving one award or a number of interrelated and interdependent awards, designed to acquire knowledge or to use or provide resources directed towards the attainment of an NIH objective or purpose.

11. Training - The development of skills of scientific and professional personnel for research, development, and related activities of importance to the R&D missions of NIH.

F. Policy:

NIH awarding units will apply the following criteria for selecting contract, cooperative agreement, and grant instruments to establish appropriate relationships between NIH and performer organizations for the conduct of extramural R&D activities:

1. Assistance - Assistance instruments are appropriate when the NIH intends primarily to stimulate, support, or assist a particular research development, training, or related program activity conducted by a recipient under specific legislation authorizing such assistance.

a. Grants are appropriate when NIH staff has no substantial programmatic involvement with the recipients during performance of the assistance activities.

b. Cooperative agreements are appropriate assistance instruments when NIH staff has substantial programmatic involvement with the recipients during performance of the activities.

2. Acquisition - Contracts shall be used for all acquisition, i.e., when NIH intends primarily to obtain goods, services, research studies, surveys, systems, or property for the direct benefit or use of NIH or other Government agencies; these agencies may, in turn, intend to provide the end-products or results to non-Government parties, including the general public.

G. Ancillary Considerations:

The criteria in F.1. and 2. must be the only determinants in the selection of each extramural award instrument. Other factors or conditions may be considered but do not influence the selection process.

1. Program Requirements- Adequate communications with R&D performer communities are essential to implement all NIH extramural programs. Such communications, by well-established mechanisms in appropriate media, serve to inform extramural performers of R&D priorities for specific programs.
 - a. Under assistance mechanisms, NIH identifies general or specific program areas for support, and the performers define and implement the specific aims, objectives, and approaches for their awarded project activities.
 - b. When acquisition is indicated, NIH may define specific problems or objectives in a Request for Proposals (RFP), asking offerors to submit their creative or innovative approaches to the contemplated activities. Or NIH may specify both the nature of and desired approaches to performing the activities, with the RFP then requesting offerors to describe their capabilities to accomplish the stated requirements.
2. R&D Category- Every program, activity, or project requires individual determination as to which award instruments fits the criteria in Section F above. While certain mechanisms may predominate for certain categories of extramural projects, every award instrument may reasonably be expected to be available for the full spectrum of projects, from basic and applied research, to development and demonstration.
3. Review Needs- Competent, objective, technical and administrative review and evaluation of applications and proposals by qualified advisory groups are vital to the maintenance of high quality in all NIH extramural project awards. Adequate procedures exist to permit review and award processes for all award instruments within reasonable time frames.

H. Concomitant Interrelationships:

The uses of different award instruments establish different responsibilities on, and interrelationships between, NIH and award recipients. While these are mentioned in other policy issuances, they may be summarized briefly here.

1. Project Development
 - a. Planning of projects under assistance awards is the responsibility primarily of applicant institutions, which submit applications on their own initiative, or in response to general program announcements or more specific guidelines in Requests for Applications (RFAs).
 - b. NIH planning of activities is expected for contract projects, to ensure

that they develop in accordance with established program requirements. The negotiated contracts incorporate specific statements of work to be performed, manner and schedules of performance, and other characteristics of the services or end-products being acquired, based on the description of work negotiated with the selected offerors. (See also Section G.1.b., above.)

2. Project Conduct

a. Awardee institutions are primarily responsible for implementing and conducting projects under assistance awards. NIH staff periodically reviews progress to ensure that the projects continue to conform to the general purposes and conditions of the awards. Under cooperative agreements NIH shares responsibility with performers by providing program advice and technical assistance to help achieve project objectives. The assistance nature of NIH staff involvement requires that NIH participation, recommendations, or decisions affecting conduct of the activities be conducted in a helpful manner. Staff should avoid tendencies to dominate or control awardees' activities, should conduct adequate discussions and negotiations with performer organizations, and should provide special review procedures whenever disagreements might arise over NIH actions that affect awardees' performance. The special reviews in no way affect the right of a recipient to appeal an adverse determination under 42 CFR Part 50, Subpart D and 45 CFR Part 16.

b. NIH specifies project requirements and activities for contract projects and ensures they proceed in accordance with negotiated contract terms and conditions. NIH staff closely monitors technical and administrative performance, collaborates with the performer as required during the activity, and requires responsiveness by the performer in case program developments necessitate changes in directions of the effort, as established by contract modifications.

3. Data Rights and Uses- NIH generally has rights to data developed under contracts, consistent with the acquisition of the services performed or the results obtained, and is responsible for arranging for appropriate dissemination of findings and other results from the activity. Awardees have primary rights to their data developed under assistance awards; and NIH has rights of access to those records. NIH may assist cooperative agreement awardees in decisions on publication of findings and interpretations, recognizing, however, that those results are not primarily for Government benefit or use.

I. Implementation:

1. Current Programs and Projects- BIDs will review their programs periodically to ensure that all extramural awards are consistent with legal requirements and with the selection criteria outlined in Section F., above. Whenever current

award instruments seem inappropriate in the light of those criteria, staff of the awarding unit may discuss the situation with the Office of Extramural Research and Training and the Division of Contracts and Grants, NIH, as appropriate, to help select and possibly act on:

- a. whether it would be feasible to transfer the projects to the more appropriate instrument;
- b. what procedures are necessary to accomplish the transfer, from one mechanism to another, including appropriate application/proposal review and reprogramming of funds; and
- c. when the preferable opportunity will occur for a change, e.g.,
 - (1) when a grant or cooperative agreement project requires competitive continuation, or
 - (2) when a contract project is to be renewed on the basis of contract extension or newcontract award.

2. New Programs and Projects- Prior to announcing new program areas, BID program officials in collaboration with both grant and contract officers, will select which projects should be awarded as grants, cooperative agreements, or contracts, under the criteria in Section F., and will document the rationales for the selections. The grant and contract officers must certify at time of award that the proper mechanism has been utilized.

a. Solicited Contract Proposals and Invited Grant/Cooperative Agreement Applications- NIH policies and procedures currently provide special requirements for BID and OD/NIH reviews of Requests for Applications (RFAs) for grants and cooperative agreements, and of contract Requests for Proposals (RFPs).

b. Unsolicited Proposals and Applications- Determinations must be made as early as possible following receipt, regarding whether these applications and proposals are appropriate for the award instrument sought.

(1) Grant Applications- The DRG Referral Branch may identify any questions as to the appropriateness of grant support for specific applications, and will communicate pertinent comments to the assigned BIDs, who will make the definitive selections of the correct mechanisms. BIDs might also identify circumstances when projects defined in grant applications would be better awarded as cooperative agreements.

(2) Cooperative Agreement Applications- Since the selection of the cooperative agreement mechanism is a BID responsibility, a

valid cooperative agreement application should rarely reach NIH without previous BID decision and announcement. Any uninvited application signifying an interest in a cooperative agreement award should necessarily document the nature of NIH staff involvement intended, and the assigned BID will determine whether that mechanism is reasonable.

(3) Contract Proposals- BIDs receiving unsolicited proposals have responsibility for determining the validity of the contract mode. For those contracts that require OD/NIH review, final determinations will be made during the OD/NIH review of the pertinent Justification for Acceptance of Unsolicited Proposal.

Any BID actions to change proposed awards to mechanisms other than those suggested by applicants/offerors should include adequate communications with the submitting institutions and investigators, as well as with appropriate OD/NIH offices as required.

J. Deviations:

If circumstances develop in actual or potential relationships with award recipients, where adherence to this policy would seriously disrupt a program or adversely affect awardees, the BID should request an exception. These requests should:

1. state whether the exception is requested for a complete program, a class of awards, or an individual award, and what time elements will be involved;
2. explain why an exception is requested, including statutory, program, or other circumstances;
3. state what the BID would do if an exception is not granted, and what would be the implications in this eventuality; and
4. justify any extraordinary circumstances that pertain when the BID requests authority to apply Section 4(2) of PL 95-224, to use contract(s) regardless of other sections of the law, to achieve program purposes and goals.

BID Directors will submit memoranda for these exceptions through the Deputy Director for Extramural Research and Training (DDERT), NIH and the Director, NIH, to the Director, Office of Management, PHS. Acceptable justification will then be processed through channels for required OMB approval. Upon receipt of approved requests, the DDERT will advise the BIDs regarding the results of PHS-OMB review.

K. Additional Information:

For further information on this manual chapter, contact the Office of Extramural Programs Management, OERT, on 496-2241.

L. Additional Copies of this Chapter:

For extra copies of this chapter, send a Form NIH 414-5 to the P&RB, DAS, in Bldg. 31, Room B3BE07.

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